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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,824	10/19/2005	Lynne Rainen	P-5729	7737
26253 7590 09/17/2007 DAVID W. HIGHER, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			EXAMINER UNDERDAHL, THANE E	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 09/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,824	Applicant(s) RAINEN ET AL.	
	Examiner Thane Underdahl	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-76 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. The groups and the claims they include are as follows:

Group I, claim(s) 1-27, drawn to an apparatus for containing a biological sample, comprising:
a container having a reservoir portion for receiving the sample; and a stabilizing agent in the reservoir of the container, the agent comprising a caspase inhibitor.

Group II, claim(s) 28-35, drawn to a tube for collecting and stabilizing a biological sample; comprising: a first end, a second end and at least one interior wall defining a
reservoir portion for receiving the sample; at least one stabilizing agent in the reservoir of the container, the stabilizing agent comprising a caspase inhibitor; a thixotropic polymeric gel in the reservoir; and an element for maintaining separation of the stabilizing agent and the gel.

Group III, claim(s) 36-50, drawn to a tube for collecting and stabilizing a biological sample, comprising: a first end, a second end and at least one interior wall defining a reservoir portion for receiving the sample; at least one stabilizing agent in the reservoir of the tube the agent
comprising a caspase inhibitor; and a mechanical separating element in the reservoir.

Group IV, claim(s) 51-60, drawn to A method of stabilizing a biological sample, comprising: providing a sample collection container; and disposing the biological sample into the collection container such that the sample is contacted with a stabilizing agent comprising a caspase inhibitor.

Group V, claim(s) 61-65, drawn to A method for making a collection container for collecting a biological sample, comprising: providing a collection container; disposing a stabilizing agent comprising at least one caspase inhibitor into the container; lyophilizing the stabilizing agent;

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evacuating and sealing the container; and sterilizing the container.

Group VI, claim(s) 66-71, drawn to A method for treating, comprising the steps of collecting a cell population that comprises hematopoietic stem cells, wherein the cell population is collected in a container comprising one or more caspase inhibitors; and administering at least a portion of the collected cell population into a patient.

Group VII, claim(s) 72-76, drawn to A method for treating, comprising the steps of: performing a leukapheresis process to collect a cell population that comprises hematopoietic stem cells, wherein the cell population is collected in a container comprising one or more caspase inhibitors; and administering at least a portion of the collected cell population into a patient.

(a) An international or national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those invention involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the **CLAIMED INVENTIONS, CONSIDERED AS A WHOLE, MAKES OVER THE PRIOR ART.**

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because the invention AS CLAIMED is known in the art, see U.S. Patent # 6,184,210 and thus no special technical feature unites these inventions in a category. . The special technical feature being a biological sample container that comprises a caspase inhibitor.

U.S. Patent # 6,184,210 teach the inventive concept of Group V in Example 21 (col 17) a method to stabilize a biological sample in a container with a caspase inhibitor.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl


Leon B. Lankford Jr